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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,530	12/18/2001	Pierre Legrain	EGYPSA 3.0-001	5557

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/023,530

Applicant(s)

LEGRAIN ET AL.

Examiner

Daniel M Sullivan

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-- **Th MAILING DATE of this communication appears on the cover sheet with the corresp ndenc address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 7 and 8, drawn to a complex of protein-protein interactions as set forth in SEQ ID NO:2 and 3 and fragments or variants thereof, classified in class 530, subclass 350.
- II. Claims 2, 6, 9, 10, 11 and 13 drawn to a complex of polynucleotides set forth as SEQ ID NO:1 and 3, and fragments and variants thereof, a vector and host cell comprising the polynucleotides and a pharmaceutical composition comprising the host cell, classified in class 424, subclass 93.2.
- III. Claim 3, drawn to a recombinant host cell expressing the polypeptides as defined in Table 1, classified in class 435, subclass 254.2.
- IV. Claim 4, drawn to a method for selecting a modulating compound comprising using the host cell of claim 11, classified in class 435, subclass 29.
- V. Claim 5 and 12, drawn to a modulating compound identified by the method of Group IV and a pharmaceutical composition comprising said modulating compound, classified in class 514.
- VI. Claim 14, drawn to a protein chip comprising the polypeptides of Group I, classified in class 436, subclass 518.
- VII. Claim 15, drawn to a monoclonal antibody against the polypeptide of Group I, classified in class 530, subclass 387.1.

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The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to specific polypeptides (Invention I) and host cells comprising unidentified polypeptides (Invention III). As the polypeptides comprised by the host cell are not the polypeptides of Group I, the Inventions are unrelated.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention I can be used in a materially different process such as to raise an antibody.

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Inventions I and V are unrelated. The inventions are directed to structurally and functionally distinct molecules.

Inventions I and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed is not solely dependent upon the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed is not solely dependent upon the particulars of the subcombination as claimed because patentability of a protein chip is derived from the aggregate of polypeptides comprised by the chip and not any single polypeptide. The subcombination has separate utility such as to raise an antibody or to use in the method of Group IV.

The polypeptides of Invention I are related to the antibodies of Invention VII by virtue of binding affinity. Although the polypeptides and antibodies are related since the antibody binds to the polypeptide and can be raised by immunization with the polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the polypeptide may be used for processes other than the production of the antibody, such as a standard in an assay for the presence of the protein.

The polynucleotides of Group II are unrelated to the Inventions of Groups III and V-VII because the inventions are directed to compositions that do not comprise the polynucleotides and are thus structurally and functionally distinct.

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The polynucleotide of Group II is related to the method of Group IV as product and process of use. However, the polynucleotide can be used in a materially different process such as a hybridization assay.

The host cell of Group III is unrelated to the Inventions of Groups IV-VII because Invention IV is directed to a method of using a materially different product (i.e., the host cell of Group II) and the compositions of groups V-VII do not comprise the host cell of Group III.

The method of Group IV is unrelated to the compositions of Groups VI and VII because the compositions are not disclosed as capable of use together with the method.

The method of Group IV is related to the compound of group V in that the method can be used to identify the molecule. However, the compound can be identified by a materially different process such as by assaying for modulation of the protein complex by coimmunoprecipitation.

The modulating compound of Group V is unrelated to the compositions of Inventions VI and VII because the Inventions are not disclosed as capable of use together and are structurally and functionally distinct.

The protein chip of Invention VI is unrelated to the monoclonal antibody of Invention VII because the Inventions are not disclosed as capable of use together and are structurally and functionally distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms  
March 20, 2003

*Anne-Marie Falk*  
**ANNE-MARIE FALK, PH.D**  
**PRIMARY EXAMINER**